

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

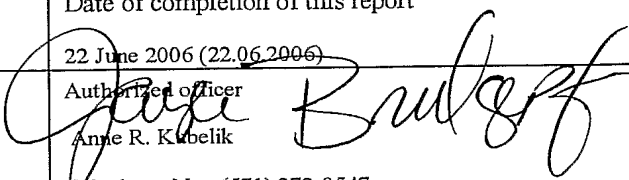
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 10 JUL 2006

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Applicant's or agent's file reference 38-21(52806)	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US04/21692	International filing date (day/month/year) 06 July 2004 (06.07.2004)	Priority date (day/month/year) 07 July 2003 (07.07.2003)	
International Patent Classification (IPC) or national classification and IPC IPC: Please See Continuation Sheet USPC: 800/279,301;424/725;424/93.2;435/418;514/2;536/23.71;530/350			
Applicant MONSANTO TECHNOLOGY, LLC			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 05 May 2005 (05.05.2005)		Date of completion of this report 22 June 2006 (22.06.2006)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		 Authorized officer Anne R. Kubelik Telephone No. (571) 272-0547	

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:
 pages 1-77 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☒ the claims:
 pages 78-83 as originally filed/furnished
 pages* NONE as amended (together with any statement) under Article 19
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☒ the drawings:
 pages 1-3 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest, and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ neither restricted the claims nor paid additional fees
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:

Please See Continuation Sheet

4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts
 - ☐ the parts relating to claims Nos. _____

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/21692

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims <u>5-11, 13, 15-21, 24-47</u>	YES	
	Claims <u>1-4, 12, 14, 22-23</u>	NO	
Inventive Step (IS)	Claims <u>5-10, 13, 15-21, 24-47</u>	YES	
	Claims <u>1-4, 11-12, 14, 22-23</u>	NO	
Industrial Applicability (IA)	Claims <u>1-47</u>	YES	
	Claims <u>NONE</u>	NO	
<p>2. Citations and Explanations (Rule 70.7)</p> <p>Claims 1-47 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.</p> <p>Claim 5-10, 13, 15-21 and 24-47 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest Nucleic acids of SEQ ID NOs:1-4, 6-12 or 15-33.</p> <p>Claims 1-4, 12, 14 and 22-23 lack novelty under PCT Article 33(2) as being anticipated by HWANG et al (1998, System Appl. Microbiol. 21:179-184). HWANG et al teach a <i>Bacillus thuringiensis</i> nucleic acid that hybridizes to SEQ ID NO:5 and teach the protein it encodes.</p> <p>Claims 1-4, 12, 14 and 22-23 lack novelty under PCT Article 33(2) as being anticipated by BERRY et al (2002, Appl. Environ. Microbiol. 5082-5095). BERRY et al teach a <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> nucleic acid that hybridizes to SEQ ID NO:5 and teach the protein it encodes.</p> <p>Claims 1-4, 11-12, 14 and 22-23 lack an inventive step under PCT Article 33(3) as being obvious over BERRY et al (2002, Appl. Environ. Microbiol. 5082-5095) in view of PLANT GENETIC SYSTEMS, NV (1991, EP 451,878). The claims are drawn to a method of controlling a coleopteran pest by contacting it with protein encoded by a nucleic acid that hybridizes to SEQ ID NO:5. BERRY et al teach a protein encoded by a <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> nucleic acid that hybridizes to SEQ ID NO:5. PLANT GENETIC SYSTEMS teaches a method of controlling a coleopteran pest by contacting it with <i>Bacillus thuringiensis</i> protein (pg 26-58). One of ordinary skill in the art would have been motivated to substitute the nucleic acids taught by BERRY et al in the method taught by PLANT GENETIC SYSTEMS because of the importance of <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> in pest control (BERRY et al, pg 5082, left column).</p>			

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Continuation of IPC:

C12N 15/32(2006.01),15/82(2006.01),1/21(2006.01);C07K 14/325(2006.01);C12P 21/02(2006.01),19/34(2006.01);A01N 63/02(2006.01),65/00(2006.01)

IV. 3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Groups 1-24, claim(s) 1-9, 14-24 and 27-47, drawn to a nucleic acid, host cells, bacteria, plants, seeds, and constructs comprising it, a method of using it to detect a nucleic acid, and a method of making the plants, wherein

Group 1 is drawn to SEQ ID NO:2;

Group 2 is drawn to SEQ ID NO:3;

Group 3 is drawn to SEQ ID NO:5;

etc.

Groups 25-31, claim(s) 10-13 and 25-26, drawn to a protein and a method of using it to control a pest, wherein

Group 25 is drawn to SEQ ID NO:2;

Group 26 is drawn to SEQ ID NO:4;

Group 27 is drawn to SEQ ID NO:6;

etc.

The inventions listed as Groups 1-31 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups 1-31 appears to be t1C insecticidal proteins from *Bacillus thuringiensis*.

However, MONSANTO TECHNOLOGY, LLC (WO 01/87940) teach the t1C insecticidal protein t1C851 and a nucleic acid encoding it (pg 27, line 14, to 28, line 4; pg 65, line 21, to pg 67, line 8). This nucleic acid would hybridize to at least one of SEQ ID NOs:2, 3,5, 7, 9, 11, 12, 15-30 or 32 under "specific hybridization conditions", which the instant specification defines as conditions that enable identification of distantly related sequences (pg 21, lines 10-15). Thus, claim 1 among others, is not novel.

Therefore, the technical feature linking Groups 1-31 is not special and the Groups are not so linked under PCR Rule 13.1.

Applicant is reminded that a determination regarding unity of invention is made without regard to whether a group of inventions is claimed in separate claims or as alternatives within a single claim (MPEP 1893(d), last paragraph).